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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/825,992	TUTUNCU ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8,10-21,23 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,10-21,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed May 5, 2006 is acknowledged. Claims **1-5, 7-8, 10-21, and 23-24** are pending in this application. Claims 6, 9, 22, and 25-27 stand cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-8, 10-11, 15-18, 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanke (6,231,900). Note the rejection over claims 20-21 is withdrawn in view of applicant's argument, which is found persuasive.

Hanke teaches a confectionary product for its soothing properties, sore throat and relief of symptoms associated with cough and cold. The product is administered as a throat drop or lozenge, which releases the actives upon sucking in the oral cavity. See abstract and column 1, lines 10-20. Hanke teaches the use of a separate and distinct region for a flavor composition and a cooling composition. The cooling agent taught is any agent that provides a physiological

cooling effect. See column 2, lines 55-57. The flavoring composition can be chosen from flavoring **oils** or essences. Flavoring liquids include cinnamon oil, artificial, natural, or synthetic fruit flavors such as citrus **oil** including lemon, orange, pineapple, etc. The flavoring agent may be utilized in an amount of 0.1-4%. See column 7, lines 5-26.

In a preferred embodiment, the cooling composition comprises an acidulating agent, which is an organic acid such as tartaric acid or preferably citric acid. Hanke teaches that the precise level will depend on the raw materials used and the consistency required. Suitable levels are from about 0.3% to about 1.5%, preferably from about 0.4% to about 1.3%, more preferably from about 0.5% to about 1.2% by weight of the cooling composition. Varying the level of the acidulating agent allows control of the dissolution/disintegration rate of the cooling composition and permits differentiation of the release profile of the cooling agent relative to that of the flavor from the flavor composition. See column 6, lines 1-20. Hanke teaches that when the confectionery product takes the form of a gelatin or gum arabic pastille, and the flavor and coolant compositions have substantially the same carrier, the compositions can be adapted to provide different release profiles by using different levels of acidulating agent in the flavor and coolant compositions. The level of acidulating agent controls the solubility and disintegration rate of the composition; the higher the level of acidulating agent in a given composition (the flavor or coolant composition), the faster the composition will disintegrate in the mouth and result in early release of the flavor or coolant. Thus, the level of acidulating agent by percent weight of the flavor composition may be greater or lesser than the level of acidulating agent by percent weight of the coolant composition. See column 8, lines 1-24.

The carriers are sugar or sugar-free bases. The sugar base is selected from sucrose, fructose, glucose, or corn syrup and the sugar-free base is selected from sorbitol or xylitol. See column 5, lines 55-63 and column 6, lines 45-50.

The examples utilize a sweetened gelatine mixture comprising 7.1% gelatine, 26.1% sucrose, 44.6% glucose syrup, and 22.2 water. Example 1 discloses the two separate compositions wherein A contains 97.8% of a sweetened gelatin mixture, 1.4% citric acid, and 0.6% of an orange flavor (lipid since Hanke utilizes a flavor oil). Composition B contains 99% of a sweetened gelatin mixture, 0.7% citric acid (acidulent), and 0.1% menthol (cooling compound). Hanke discloses the use of a mold in which the respective composition is placed and each composition has a surface on the exterior of the product. The amount of sucrose and glucose in the composition is approximately 69%.

Hanke does not exemplify the acidulent (citric acid) in a higher concentration in the coolant composition.

Firstly, it should be noted that composition A, Hanke's flavor composition, reads on the instantly claimed oral comfort region comprising a lipid since Hanke teaches the use of a flavor oil in this region. Further, the "orange flavor" in composition A is a flavor oil since Hanke makes a distinction between "flavors" which Hanke teaches as citrus oils and "essences". See column 7, lines 10-20. Composition B, the coolant composition, reads on the instantly claimed salivation region, which contains the acidulent. Further, the claims recite open-ended claim language, i.e. comprising, the "acidulent" may be in both regions with the proviso that the respective agent is concentrated in the given area. In the exemplified formulation, the flavor composition has a higher concentration of the acidulent; however it would have been obvious to one of ordinary

skill in the art at the time the invention was made to look to the guidance provided by Hanke and utilize the acidulent in a higher concentration in the coolant composition. One would have been motivated to do so since Hanke teaches that varying the level of the acidulating agent allows control of the dissolution/disintegration rate of the cooling composition and permits differentiation of the release profile of the cooling agent relative to that of the flavor from the flavor composition. Thus, Hanke teaches that a higher level of acidulating agent provides a composition that disintegrates more rapidly in the mouth resulting in earlier release of the flavor or coolant. Therefore, it would have been prima facie obvious to utilize a higher concentration of acidulent in the coolant composition if one desired to have the coolant release earlier than the flavor composition. Further, although Hanke prefers that the flavor composition comprises a higher concentration of the acidulent, disclosed examples and preferred embodiments do not constitute a teaching away form the broader disclosure or nonpreferred embodiment". In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

With regard to claims 4-5, although Hanke utilizes a sugar base, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Hanke and utilize a sugarless base. One would have been motivated to do so with an expectation of similar results and success since Hanke teaches the carrier may be a sugar or sugarless base. Therefore, the substitution of the exemplified sugar base with the instant sugarless base is prima facie obvious.

With regard to claim 11, although example 1 teaches the flavor oil in the amount of 0.6%, column 7 suggests incorporating the flavor in an amount of 0.1-4%, which overlaps the instant range of 1-20%. The manipulation of the concentration of the flavor in view of the guidance

provided by Hanke is prima facie obvious. One would have been motivated to manipulate the amount of flavor oil utilized depending on the potency of the flavor desired. Further, it should be noted that generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical. See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regard to claim 20 directed to a method of treating xerostomia, it is the examiner's position that the preamble is implicitly met since the prior art discloses the same method steps of administering a confectionary product comprising two distinct areas of an oral comforting region and a salivation region to the oral cavity to the same population (those with throat irritation, which is a symptom of xerostomia).

Response to Arguments and Rule 132 Declaration

Applicant argues that one of ordinary skill would not recognize that orange flavor oil is a lipid. Applicant argues that lipids as generally understood by a skilled artisan, refers to glycerol esters of fatty acids. Applicant argues that essential oils do not read on lipids since essential oils contains terpenes, alcohols, aldehydes, ketones, and esters. Applicant argues that orange flavor oil does not lubricate, moisten or coat the oral cavity.

Applicant's arguments filed 5/5/06 have also been fully considered but they are not persuasive. The examiner points to Grant & Hackh's, Chemical Dictionary, Fifth Edition, 1987 wherein lipid is defined as:

> Lipid: A generic term for fats and lipoids, the alcohol-ether-soluble constituents of protoplasm, which are insoluble in water. They comprise the fats, fatty oils, essential oils, waxes, sterols, phospholipids, glycolipids, sulfolipids, aminolipids, chromolipids (lipochromes), and fatty acids.

The examiner points to paragraph [0061] of US 20050181036:

> The term "lipid" is used in its conventional sense as a generic term encompassing fats, lipids, alcohol-ether soluble constituents of protoplasm, which are insoluble in water. Lipids may be fats, fatty oils, essential oil, waxes, steroid, sterols, phospholipids, glycolipids, sulpholipids, aminolipids, chromolipids, and fatty acids. The term encompasses both naturally occurring and synthetic lipids.

The examiner points to paragraph to column 2, lines 33-43 of US 4790998:

> The lipid component may be composed of one or a number of water insoluble components, including glycerides, phosphoglycerides, sterols, waxes, terpenes, etc. Specific examples include vegetable oil, partially hydrogenated vegetable oil, animal fat, lecithin, essential plant oils, etc.

Thus, applicant's argument that "lipids' refers to glycerol fatty esters is unpersuasive since the specification does not explicitly define the term as such and secondly a skilled artisan would recognize that an essential oil is a lipid as evidenced by Grant & Hackh's, Chemical Dictionary; US 20050181036; and US 4790998.

The Rule 132 under 37 CFR 1.132 filed 5/5/06 is insufficient to overcome the rejection of claims 1-5, 7-8, 10-11, 15-18, 20-21, 23-24 based upon Hanke (6,231,900) as set forth in the last Office action because: Firstly, the examiner notes that the Rule 132 Declaration submitted on 5/5/06 is an opinion declaration without the submission of objective evidence. The instant affidavit only states a conclusion that essential oils do not read on lipids. "Although an affidavit or declaration which states only conclusions may have some probative value, such an affidavit or declaration may have little weight when considered in light of all the evidence of record in the application." See MPEP 716.01 (c). Thus, the Rule 132 declaration only states a conclusion without factual evidence and in light of the evidence provided by the examiner the affidavit does not overcome the rejection.

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanke (6,231,900) in further view of National Institute of Dental and Craniofacial Research, NIH publication, June 1999.

As set forth above, Hanke teaches a confectionary product for its soothing properties, sore throat, and relief of cold like symptoms. The product is administered as a throat drop or lozenge, which releases the actives upon sucking in the oral cavity. See abstract and column 1, lines 10-20. Hanke teaches the use of a separate and distinct region for a flavor composition and a cooling composition. The cooling agent taught is any agent that provides a physiological cooling effect. See column 2, lines 55-57. The flavoring composition can be chosen from flavoring **oils** or essences. Flavoring liquids include cinnamon oil, artificial, natural, or synthetic fruit flavors such as citrus **oil** including lemon, orange, pineapple, etc. Example 1 discloses the two separate compositions wherein A contains 97.8% of a sweetened gelatin mixture, 1.4% citric acid, and 0.6% of an orange flavor (lipid since Hanke utilizes a flavor oil). Composition B contains 99% of a sweetened gelatin mixture, 0.7% citric acid (acidulent), and 0.1% menthol (cooling compound). Hanke discloses the use of a mold in which the respective composition is placed and each composition has a surface on the exterior of the product. The amount of sucrose and glucose in the composition is approximately 69%.

Although Hanke teaches the use of the confectionary product for providing soothing properties, Hanke does not specifically teach the use of the product to treat xerostomia.

The NIH publication teaches xerostomia (dry mouth) is caused by several factors such as the side effects of medication, diseases, chemotherapy, etc. The symptoms include sticky, dry mouth, trouble chewing, swallowing, tasting, a burning feeling in the mouth, a dry feeling in the

throat, cracked lips, a dry tongue, and mouth sores. The publication teaches methods of treating xerostomia include, chewing sugarless gum or sucking on sugarless gum to stimulate saliva flow. Candies that have citrus, cinnamon, or mint are good choices.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Hanke and the publication NIH publication on xerostomia and utilize Hanke's composition to treat xerostomia. One would have been motivated to do so since Hanke teaches a sugarless confectionary product containing citrus flavors and menthol to and the NIH publication teaches sucking on sugarless candies, particularly ones that contains citrus and mint, treat xerostomia. Furthermore, a skilled artisan would have expected success since Hanke teaches the confectionary provide soothing properties and the symptoms of dry mouth include a burning feeling in the mouth and dry feeling in the mouth, and mouth sores.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,231,900 to Hanke (6231900) in view of US patent 6,099,880 to Klacik et al.

As set forth above, Hanke discloses preparation of a confectionary product to relieve sore throat and cough containing a separate and distinct region for a flavor composition and a cooling composition. Hanke discloses the use of a mold in which the respective compositions are placed. (Note example 1)

The reference does not teach a mold having a ridge to separate the components.

Klacik et al discloses a patterned candy containing agents such as sugar, sugar alcohol, coconut oil, and flavors. Klacik et al teach the mold having separate region and depositing mixtures in each segment to form a product with visually distinct regions. Klacik teaches this method is a simple method of forming distinct regions. See column 1, lines 30-50.

It is would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the Hanke and Klacik et al and utilize a mold with a ridge. One would have been motivated to do so since Klacik et al teach an economical and simple process of producing a product having distinct regions using a mold having a ridge. Therefore, it is obvious to utilize a ridge to further maintain the separation and distinction of each respective region.

Response to Arguments

Applicant argues that Klacik does not overcome the deficiencies of Hanke. Applicant argues that Klacik does not teach an acidulent or a salivation region.

Applicant's arguments filed 5/5/06 have been fully considered but they are not persuasive. The merits of Hanke have been discussed above and it is the examiner's position that Hanke renders the instant invention prima facie obvious. The examiner further points out that Klacik is not relied to teach an acidulent or a salivation region since Hanke is not deficient in this sense. Klacik is relied upon for its specific teaching of utilizing a mold with a ridge. The applicant has not argued the merits of this rejection is particular and thus it is the examiner's position that claim 19 is rendered obvious over Hanke in view of Klacik.

Claims 1-5, 7-8, 10-14, 17, 20, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al in view of WO 99/579427 to Le et al.

Cherukuri et al disclose encapsulated flavor with bioadhesive properties. The compressed confectionary provides controlled release of the flavor and a unique mouthfeel by using bioadhesives. The compressed tablet is characterized by discrete phases contained within. See Figure 5 and 6 wherein both phase 1 and 2 have a surface on the exterior of the product.

The compressed tablet include: (a) a first flavor ingredient present in an amount from about 0.1% to 0.5% by weight of a hydrophilic composition with which it is intimately bound to provide instantaneous delivery of the active ingredient; and (b) a second flavor ingredient present in an amount of from about 3% to 30% by weight of a hydrophobic encapsulating composition containing a bioadhesive so as to provide delivery of the second flavor ingredient over a period of time while both the tablet and encapsulated flavors adhere to the moist areas of the oral cavity.

The confectionary compressed tablet is made of a sugar or sugarless base. See column 8, lines 66-67 and column 10, lines 40-45. Sugars taught include sucrose, glucose, dextrose, fructose, and sugar alcohols include sorbitol, mannitol, and xylitol. See column 9, lines 7-21. Emulsifiers (surfactants) are taught in an amount of 2-7%. See column 8, lines 40-55.

Cherukuri also teaches that in addition to encapsulated flavor ingredients, a bio-effecting agent such as breath fresheners, breath deodorants, antigingivitis agents, and combinations thereof may also be used. See column 7, lines 30-45.

Table II, example III discloses a product wherein the shell component contains 97.676% sugar, 0.748 % of a breath deodorant (copper gluconate), 0.234% lubricant, 1.280% flavor beads, 0.062% liquid flavor. This shell region reads on instant "salivation region" since this region contains the bio-effecting agent (the breath freshener). The core comprises 40.32% fat encapsulation material of Table I and 59.68% of a diluent. Table I discloses a fat encapsulation containing 48% partially hydrogenated soybean oil, 5% glycerol monostearate, 10% vegetable oil, 2% flavor oil, and 20% bioadhesive. This core region read on instant "oral comfort region" since this phase predominantly comprises lipids. Cherukuri teaches the diluent may be selected from lactose (sugar), microcrystalline cellulose, starch, talc, sorbitol, mannitol, xylitol, maltitol,

xylitol, other sugar alcohols or sugars. See column 8, lines 60-65. Note that this diluent reads on applicant's confectionary base of the oral comfort region. The tablet is made by mixing each respective composition with the respective components separately and then the core is compressed into the shell portion. See column 10, line 40 to column 11, line 28.

Although Cherukuri teaches the use of bioeffecting agents in the shell portion, Cherukuri does not teach the specific use of an acidulent in the shell portion.

Le teaches co-processed comestible, confectioneries, pharmaceuticals, and dentifrices comprising an acid and water-soluble crystalline compounds. Le teaches that the prior art conventionally uses acidulents in comestible for a variety of reasons. For instance, acidulents may be used to increase saliva production for the treatment of xerostomia and dry mouth; the use of acids to soften plaque on teeth; as flavor enhancers to improve the release of flavor in confectionary products such as hard candies. See page 1. Le teaches the acidulent may be inorganic or organic acids including phosphoric acid, citric acid, malic acid, succinic acid, fumaric acid, ascorbic acid, etc. see page 5, lines 13-25. The acidulent is utilized in an amount of 0.2% of the entire composition (note example 4 in combination with Table 2 formulation wherein the acidulent is 5.5% of the coprocessed formulation and the coprocessed formulation is 3.75% of the composition)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Cherukuri et al and Le et al and utilize an acidulent as the bio-effecting agent in the shell portion of Cherukuri's composition. Firstly, one would have been motivated to do so with a reasonable expectation of success since Cherukuri teaches the use of bio-effecting composition in the composition; thus a skilled artisan would have been motivated

to utilize an acidulent in Cherukuri's example as the bio-effecting agent in place of the breath freshener if one desired to treat xerostomia and dry mouth rather than halitosis. Secondly, one would have been motivated to utilize an acidulent in the shell portion since Cherukuri teaches the shell portion provides the release of the first flavor (the rapid release portion) and thus a skilled artisan would have been motivated to utilize an acidulent in the shell portion since Le teaches acidulents are conventionally utilized to improve and enhance the release of the flavor. Therefore, a skilled artisan would have been motivated to utilize an acidulent in the shell portion to increase the rate of release of first flavor in the hydrophilic portion (shell portion).

With regard to claim 14, the manipulation of the concentration of emulsifier in the core composition of example III is considered to be obvious to one of ordinary skill. The examples utilize a range of 5%, however one would have been motivated to utilize the instant range of 0.5-4% since Cherukuri teaches the emulsifier may be utilized in a range of 2-7%. Therefore, the range taught by Cherukuri overlaps the instant range.

Response to Arguments

Applicant argues that it was agreed that limiting the claims to "acidulent" would overcome Cherukuri. Applicant contends that the examiner has not limited the number of issues and "now alleges that even with this element (the acidulent) entirely absent from the primary references, it would have been obvious....".Applicant argues this is improper.

Applicant's arguments filed 5/5/06 have been fully considered but they are not persuasive. The examiner notes that the Office Action of 6/14/05 withdrew a rejection based on anticipation over US '659. The examiner made a subsequent rejection based on obviousness over US '659. The examiner points out that the rejections made in the Office Action of 6/14/05 are

materially different rejections than the instant rejection US '659 in combination with WO 99/579427 is used to reject the instant claims. Therefore, the amendment to limit the claims to "acidulent" overcame the anticipation rejection over US '659 and the obviousness rejection over US '659 *itself*. However, the withdrawal of these fundamentally different rejections (based on limiting the claims to "acidulent") is not equivalent to the assertion that US '659 in combination with another reference cannot render the instant invention obvious.

Applicant argues that Cherukuri does not teach an acidulent. Applicant argues Cherukuri only teaches discrete portions as an alternative embodiment only. Applicant argues that Le is directed to a different problem of degradation of acid-sensitive components. Applicant argues that the examiner agreed to drop the rejection made over Le. Applicant argues Le does not teach an acidulent and salivation region in concentrated areas.

Firstly, the examiner out that the inventive nature of the solid dosage form taught in US '659 is that it has "at least two discrete phases". In the first embodiment, the first phase is structurally supportive of a compressed tablet shape and substantially envelopes the second phase. In the second embodiment, the first phase is generally the middle and circumferential portion and the second phase has been fixed on either sides. The resulting tablet is depicted in Figure 5 and has a cross-section as shown in Figure 6. See column 11, lines 39-44. The examiner points out that disclosed examples and preferred embodiments do not constitute a teaching away form the broader disclosure or nonpreferred embodiment". In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Thus, alternative embodiments are permitted in the use of a rejection to render the claims obvious.

Secondly, the examiner points out that Cherukuri teaches two discrete and different phases; therefore Le does not need to teach a dosage form with discrete portions with a acidulent and salivation region since Cherukuri is not deficient in this sense. The examiner only relies on Le for the specific teaching of utilizing acidulents as the active agent of choice. Le is in the same field of endeavor and Le need not teach the same type of dosage form as Cherukuri for the combination to be proper. Moreover, it should be noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Lastly, examiner notes that Cherukuri does not teach an acidulent and hence the rejection is made under obviousness and *in view* of WO 99/579427.The examiner's motivation to combine the references and as set forth clearly in the office action is the following: Cherukuri teaches the use of bio-effecting agents such as breath fresheners, breath deodorants, antigingivitis agents, in one phase. Le teaches acidulents are conventional actives used in the art to increase saliva production for the treatment of xerostomia and dry mouth and the use of acids to soften plaque on teeth. The examiner provides two reasons a skilled artisan would have been motivated to use an acidulent based on the *combined* teaching of Cherukuri and Le. Firstly, a skilled artisan would have been motivated to utilize an acidulent in Cherukuri's example as the bio-effecting agent in place of the breath freshener if one desired to treat xerostomia and dry mouth rather than halitosis. Secondly, one would have been motivated to utilize an acidulent in the shell portion to

increase the rate of release of first flavor in the hydrophilic portion (shell portion) since Cherukuri teaches the shell portion provides the release of the first flavor (the rapid release portion) and Le teaches acidulents are conventionally utilized to improve and enhance the release of the flavor. The applicant has not provided any unexpected results or persuasive arguments to overcome this rejection.

Art of Interest

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US patent 4,847,090 to Della Posta et al disclose a confection piece with two or more discrete areas to provide a unique organoleptic response. However, Della Posta does not teach each region having the instant oral comforting components and the instant salivating agents respectively.

Conclusion

All the claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila S. Gollamudi
Examiner
Art Unit 1616